5.0 510K Summary

SEP - 5 2008

Applicant: Brontes Technologies, Inc. (A 3M Company)
10 Maguire Road, Suite 310
Lexington, MA 02421
Tel: (781) 541-5200

Contact: Mark Olsen

510(k) Numbers and Product Codes of equivalent devices:

Brontes Technologies, Inc. (A 3M Company), Lexington, MA
3M™ ESPE Lava™ Chairside Oral Scanner
Code: NOF; K073199

Indications for Use

The 3M™ Unitek™ Lava™ Chairside Oral Scanner is an optical impression system (CAD/CAM) used to record the topographical characteristics of teeth. Data generated from the 3M™ Unitek™ Lava™ Chairside Oral Scanner may be used in conjunction with the production of orthodontic appliances, retainers and accessories.

Device Description

The 3M™ Unitek™ Lava™ Chairside Oral Scanner is a system intended to obtain 3D images of the topographical characteristics of Teeth. The System consists of a computer, proprietary software and a hand held dental 'wand' for scanning the surface of the teeth.

Using the wand in close proximity to the teeth, the image of the teeth is communicated to the software and a 3D model is created by the software. The 3D model is then stored on disk along with pertinent patient information.

In this 510K pre-market notification, the software has been modified to adapt to the revised intended use statement, which adds a new device with the application of generating models for orthodontic appliances, retainers and accessories. An analysis of the changes to the device along with In-Vitro test data demonstrates that no new issues of safety or effectiveness are raised by the changes to the device discussed in this pre-market notification.

The 3M™ Unitek™ Lava™ Chairside Oral Scanner will be manufactured by Brontes Technologies, Inc., a 3M Company, and distributed by 3M Unitek, another 3M Company.

Performance Standards

There are no changes to the performance standards with The 3M™ Unitek™ Lava™ Chairside Oral Scanner as compared to the predicate device. The 3M™ ESPE Lava™ Chairside Oral Scanner meets the following Performance Standards:

- Tripartite Guidance – 1987 (G87-1)
- Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA

- ISO/EN 10993-1; 1997 Biological Evaluation of Medical Devices, Part I: Evaluation and Testing
- ISO/EN 10993-5; 1999 Tests for In-Vitro Cytotoxicity, 2nd Ed
- ISO/EN 10993-10; 2002 Tests for Irritation and Delayed Type Hypersensitivity, 2nd Ed
- IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC 60601-1-2 Medical Electrical Equipment – Part 1 – General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-1-4 medical Electrical Equipment – Part 1 – Medical Electrical Equipment part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems
- FDA Guidance on Dental Handpieces – (Draft) July 1995
- ISO 7405 – Pre-Clinical evaluation of Biocompatibility of medical devices used in dentistry, test methods for dental materials.
- FDA; Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices - May 2005
- FDA Guidance; Cyber Security for Networked Medical Devices Containing Off the Shelf Software
- ISO 14971 - Medical devices – Risk management – Part 1: Application of risk analysis

Conclusion:

There are more similarities than differences between the predicate devices and the 3M™ Unitek™ Lava™ Chairside Oral Scanner. The predicate device and the 3M™ Unitek™ Lava™ Chairside Oral Scanner have similar intended uses, warnings and contraindications. Both the 3M™ Unitek™ Lava™ Chairside Oral Scanner and predicate device may be used with a powder and powdering delivery system. When used in accordance with the instructions for use, by qualified personnel, the 3M™ Unitek™ Lava™ Chairside Oral Scanner is safe and effective, as indicated, for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2008

Brontes Technologies, Incorporated
C/o Mr. John Greenbaum
President
Generic Devices Consulting, Incorporated
20310 SW 48th Street
Southwest Ranches, Florida 33332

Re: K081961
Trade/Device Name: 3M™ Unitek™ Lava™ Chairside Oral Scanner
Regulation Number: 872.3661
Regulation Name: Optical Impression Systems for CAD/CAM
Regulatory Class: II
Product Code: NOF
Dated: July 8, 2008
Received: July 9, 2008

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K081961

Device Name: 3M™ Unitek™ Lava™ Chairside Oral Scanner

Indications For Use:

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Prescription Use_X_ OR Over-The-Counter Use___
(Per 21 CRF 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081961